DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 3, 2015

Medtronic CoreValve, LLC.
Matthew Lobeck
Regulatory Affairs Specialist
3576 Unocal Place
Santa Rosa, California 95403

Re: K150465
Trade/Device Name: Medtronic Confida™ Brecker Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 4, 2015
Received: May 6, 2015

Dear Matthew Lobeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Medtronic ConfidaTM Brecker Guidewire

Indications for Use *(Describe)*
The Medtronic ConfidaTM Brecker Guidewire is intended for use to introduce and position catheters during diagnostic and interventional procedures within the chambers of the heart, including transcatheter aortic valve implantation (TAVI)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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7.0 510(k) Summary in Accordance with 21 CFR § 807.92(c)

As required by the Safe Medical Devices Act of 1990, coded under Section 513, part (1)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Date Prepared:	July 21, 2015
Applicant:	Medtronic CoreValve, LLC 1851 E. Deere Ave. Santa Ana, CA 92705 U.S.A. Establishment Registration No. 2025587
Contact Person:	Matthew Lobeck Regulatory Affairs Specialist Medtronic Heart Valves Phone: (763) 514-9515 Fax: (763) 514-9521 Email: matthew.lobeck@medtronic.com
Subject Device Name:	Medtronic Confida™ Brecker Guidewire
Model Number:	GWBC30
Common Name:	Guidewire
Classification Name:	Wire, Guide, Catheter
Product Code:	DQX
Predicate Device(s):	Medtronic Confida™ Brecker Guidewire (K132623; cleared December 19, 2013)
Device Description:	The Medtronic Confida™ Brecker Guidewire was developed for use in diagnostic and interventional procedures including transcatheter aortic valve implantation (TAVI) procedures for the treatment of aortic valve disease. The Medtronic Confida™ Brecker Guidewire (model number GWBC30) is available in one size and is comprised of a stainless steel wire, 0.035" in diameter, and 260cm in length. The distal end of the Medtronic Confida™ Brecker Guidewire is comprised of a preformed 360° curved tip.

	The Medtronic Confida™ Brecker Guidewire is an external communicating device having limited (<24 hours) with circulating blood. The Medtronic Confida™ Brecker Guidewire has a polytetrafluoroethylene (PTFE) coating applied to the entire length of the device in order to aid in lubricity. The Medtronic Confida™ Brecker Guidewire is a patient contacting, single use only device and not intended for re-use or re-sterilization. The device is intended to be used only by physicians trained in percutaneous, intravascular techniques and procedures. The Medtronic Confida™ Brecker Guidewire is sterilized via Ethylene Oxide to a Sterility Assurance Level (SAL) of 10^{-6}.
Statement of Intended Use:	The Medtronic Confida™ Brecker Guidewire is intended to facilitate the placement of devices during diagnostic and interventional procedures.
Statement of Indications for Use:	The Medtronic Confida™ Brecker Guidewire is intended for use to introduce and position catheters during diagnostic and interventional procedures within the chambers of the heart, including transcatheter aortic valve implantation (TAVI).
Contraindications:	The Medtronic Confida™ Brecker Guidewire is contraindicated for patients presenting with an intolerance to anticoagulation therapy and unheparinized patients. The guidewire is contraindicated for use in the coronary arteries and in the cerebrovasculature.
Comparison to Predicate Devices:	The Medtronic Confida™ Brecker Guidewire is identical to the predicate device for the following characteristics: • Intended use • Indications for use • Contraindications • Target population • Fundamental scientific technology, including design • Operating principle • Packaging materials • Shelf life • Sterility assurance level and method of sterilization
Summary of Non-Clinical Data:	In order to demonstrate substantial equivalence of the subject device, the Medtronic Confida™ Brecker Guidewire, to the predicate device, the following non-clinical evaluations were

performed:

- PTFE Coating Adhesion Test (Coating Integrity)
- ISO Cytotoxicity Study
- ISO Maximization Sensitization Study
- ISO Intracutaneous Study
- ISO/USP Pyrogen Study Material Mediated
- ISO Acute Systematic Toxicity Study
- *In Vivo* Thromboresistance
- *In Vitro* Hemolysis Study (Modified ASTM – Extraction Method)
- C3a Compliment Activation
- SC5b-9 Compliment Activation

Conclusion:

The result of the non-clinical testing demonstrate the subject device, the Medtronic Confida™ Brecker Guidewire performs as well as the legally marketed predicate device, the Medtronic Confida™ Brecker Guidewire. Therefore, the subject device, the Medtronic Confida™ Brecker Guidewire, is substantially equivalent in intended use, performance, and fundamental scientific technology to the predicate device, the Medtronic Confida™ Brecker Guidewire (K132623).